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ATTORNEY DOCKET NO. CONFIRMATION NO. FIRST NAMED INVENTOR FILING DATE APPLICATION NO. 1919/60390-G/JPW/GJG/CMR 5191 09/728,616 12/01/2000 Arlindo L. Castelhano 7590 08/11/2003 **EXAMINER** Cooper & Dunham LLP 1185 Avenue of the Americas MCINTOSH III, TRAVISS C New York, NY 10036 ART UNIT PAPER NUMBER 1623 DATE MAILED: 08/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413) Paper No(s)	· · ·		Filelopy
## Diffice Action Summary    Traviss C Ministosh   1623	•	Application N .	Applicant(s)
Traviss C McIntosh  Traviss C McIntosh  1623  **The MAILING DATE of this communication appears in the cover sheet with the corresp indence address **-  Peri of for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  If the period for reely specified above is less than thirty (30) stays, a reply with the statutory reliemant of the 300 stays will be considered timely.  If the period for reely specified above is less than thirty (30) stays, a reply with the statutory reliemant of the 300 stays will be considered timely.  If the period for reely specified above is the earth mainting period will agries \$25 (8) (MCMT) its from the maining date of this communication.  If the period for reely specified works the mainting advantage of the statutory reliemant of the maining date of this communication, several timely filed, may reduce any ceremic plantation and agriculture.  **A procedure of the statutory relieve the mailing date of this communication, several timely filed, may reduce any ceremical patients and agriculture.  **Status**  2a) ☐ This action is FINAL.  2b) ☑ This action is non-final.  3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) ☑ Claim(s) 76-10 and 114-133 is/are pending in the application.  4) ② Claim(s) 76-98,100-110 and 114-133 is/are rejected.  7) ② Claim(s) 99 is/are objected to.  8) ☐ Claim(s) 76-98,100-110 and 114-133 is/are rejected.  7) ② Claim(s) 76-98,100-110 and 114-133 is/are rejected or b ☐ objected to by the Examiner.  Application Papers  9) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b ☐ objected to by the Examiner.  If approved, corrected drawings are required in reply to this Office action.  10) ☐ The drawing(s) f	Office Action Summary	·	
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THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 3°C FR 1.13(6). In no event, however, may a reply be limitly filed after SIX (6) MCNTIS from the mailing also of this communication.  It NO benefit or reply is specified above, the masterina relations pend within the studiony minimum of thirty (80) days will be considered inmit).  If NO benefit or reply is specified above, the masterina relations pend will help yet a will expect X(6) MCNTIS to the mailing date of this communication, even if timely filed, may reduce any.  Any reply received by the Office well then there members after the mailing date of this communication, even if timely filed, may reduce any.  Status  1)② Responsive to communication(s) filed on 24 April 2003.  2a) This action is FINAL. 2b)② This action is non-final.  3)③ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quay/e, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4)② Claim(s) 76-110 and 114-133 is/are pending in the application.  4a) Of the above claim(s) is/are allowed.  5)② Claim(s) 76-91.00-110 and 114-133 is/are rejected.  8)② Claim(s) 99 is/are objected to by the Examiner.  10) The drawing(s) filed on is/are: a)□ accepted or b)□ objected to by the Examiner.  Application Papers  9)□ The specification is objected to by the Examiner.  11)□ The proposed drawing correction filed on is/are: a)□ accepted or b)□ objected to by the Examiner.  12)□ The oath or declaration is objected to by the Examiner.  13)□ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  2)□ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  3)□ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  3)□ The translation of the foreign language provisional application has been received.  11□ Certified copies of			
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#### **Detailed Action**

### Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 13 is acknowledged.

Applicant's arguments drawn to the restriction set forth have been fully considered and have been found persuasive. The compound, method of making and method of using will be examined in the instant case, 09/728,616. An action on the merits of claims 76-110 and 114-133 is contained herein below.

## Information Disclosure Statement

Acknowledgement is made of the receipt of the IDS filed August 6, 2002 and April 24, 2003, however, the examiner has noted that the IDS filed February 15, 2002 and First supplemental IDS filed March 22, 2002 are not included in the file and the examiner has not been able to locate these. The examiner requests applicants resubmit the two IDS' again, with all non-patent literature for the examiner to consider and sign off on. The examiner can obtain all the patent documents.

### Claim Objections

Claims 105 and 125-127 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 105 is a product by process claim drawn to: "the prodrug of claim 103 wherein said prodrug is metabolized *in vivo* by esterase

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catalyzed hydrolysis". Where a product is metabolized, or by what is metabolized, is of no patentable import to the product as claimed. The product is treated on the merits of the product, not on processes associated with it. Claim 125 is drawn to "the composition of claim 124 wherein said therapeutically effective amount is effective to treat a respiratory disorder or a gastrointestinal disorder". Claims 126 and 127 further limit the gastrointestinal disorders or respiratory disorders. Products are treated on the merits of the products, not on what the products are effective against. *In re Thorpe, 227 USPQ 964, 966 (Fed Cir 1965)*.

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Claims 77-99 are objected to because of the following informalities: none of the claims end in a period. Appropriate correction is required.

Applicant is advised that should claim 124 be found allowable, claim 132 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 124 is drawn to a composition comprising the compound of claim 76 or 99 and a carrier. Claim 132 is a packaged composition comprising the compound of claim 76 or 99 and a container and directions. The limitations of the composition being in a container and including instructions are of no patentable import to the composition as claimed.

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## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 76-98 and 100-133 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 76 is indefinite wherein the claim reads, "wherein R<sub>5</sub> and R<sub>6</sub> are independently H, substituted or unsubstituted alkyl, or aryl". It is unclear if applicants intend the group to be: H; substituted or unsubstituted alkyl; or aryl: or if applicants intend the group to be: H; substituted or unsubstituted alkyl; or substituted or unsubstituted aryl. Clarity is respectfully requested.

Claim 76 includes the limitation of "substituted...alkyl". In the absence of the identity of moieties which are intended to be substituted, thus modifying an art recognized chemical compound of the alkyl moiety, described structurally or by chemical name, the identity of "substituted" would be difficult to ascertain. In the absence of said moieties, the claims containing the term "substituted" are not described sufficiently to distinctly point out that which applicant intends as their invention.

Claim 110 is indefinite wherein the claim reads, "...in a cell that is subject to **abnormal** stimulation of the A3 adenosine receptor..." It is unclear as to what is intended by "abnormal stimulation". There is nothing set forth which defines normal, and there is no limit or degree of variance from the "normal" population which applicants set forth as that which defines what is considered the "abnormal" population.

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Claim 124 comprises the term "effective amount" and is indefinite as the claim fails to state the function which is rendered effective. See *In re Frederiksen*, 102 USPQ 35 (CCPA 1954).

Claim 77 is drawn to a 7-deazapurine compound which has the functional group:

attached to the N-6 group of the 7-deazapurine, which lacks antecedent basis. This group is seen to be N-(1-ethyl-2-methyl-propyl)-acetamide, which is not a member of the Markush group of claim 76.

Claim 80 is drawn to a 7-deazapurine compound which has the functional group:

attached to the N-6 group of the 7-deazapurine, which lacks antecedent basis. This group is seen to be a 1-ethyl-3-propyl urea group, which is not a member of the Markush group of claim 76.

Claim 91 is drawn to a 7-deazapurine compound which has the functional group:

attached to the N-6 group of the 7-deazapurine, which lacks antecedent basis. This group is seen to be a 2-ethyl pyrrole group, which is not a member of the Markush group of claim 76.

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Claims 91-98 are all drawn to specific compounds and all ultimately depend from claim 76. Claim 76 defines R<sub>5</sub> and R<sub>6</sub> as: H, substituted or unsubstituted alkyl, or aryl. While the term "substituted" is held indefinite as set forth supra, because it is unclear as to what groups are being substituted, claims 91-98 lack antecedent basis because the groups associated with R<sub>5</sub> and R<sub>6</sub> are not substituted or unsubstituted alkyl or aryl groups. The standard representation for substituted is something which replaces a hydrogen atom on the alkyl or aryl group, not a compound which links alkyl or aryl groups as O does in claims 91 and 94-98, and not as N-hetero rings or with N-linking groups as in claims 92 and 93.

Claim 133 is indefinite wherein applicants define the method as "treating the product of b) under suitable conditions to provide c)..." The method claims should be drafted to describe in definite terms what is intended in the process, not what the reaction with unknown agents is to accomplish. The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. Defining the method as "reacting a and b to get c, then changing c to d, and finally d to e", does not define the method in a way to inform the public of the boundaries which are sought protection against.

All claims which depend from an indefinite claim are also indefinite. Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 76 is rejected under 35 U.S.C. 102(a) as being anticipated by Campbell et al. ("Selective A<sub>1</sub>-Adenosine Receptor Antagonists Identified Using Yeast *Saccharomyces cerevisiae* Functional Assays", Bioorganic & Medicinal Chemistry Letters, vol. 9, no. 16, 8.16.1999, pp. 2413-18).

Claim 76 is drawn to a compound represented by the structure I below, when  $R_5$  and  $R_6$  are methyl, and  $R_1$  is 2-imidazolidinone ethyl, the structure II is formed:

Campbell et al. disclose a compound 4i on page 2414, bottom table, and page 2415, product 4 of scheme 1 which is represented by t he structure:

which is identical to the compound as represented by formula II above.

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The compound of Campbell et al. is seen to clearly anticipate the compound of claim 76.

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### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Traviss C. McIntosh August 8, 2003 James O. Wilson

Supervisory Patent Examiner

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